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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,564	01/27/2000	PASCAL CLAUDE MICHEL LOUVEL	P1047/20008	6103

7590 09/16/2005

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EXAMINER

BERKO, RETFORD O

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/402,564	LOUVEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Retford Berko	1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8 and 10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

**Acknowledgement:** Applicant's amendment filed 10/04/04 is acknowledged

Applicant cancelled claims 1-7 and 9. Claims 8 and 10 remain for examination.

#### **Withdrawal of Claim Rejections:**

##### ***Claim Rejections - 35 USC § 102***

The rejection of claim 9 under 35 U.S.C. 102(b) as being anticipated by Oshlack et al (WO 96/14058) is hereby withdrawn.

##### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al (WO 96/14058).

Oshlack et al (WO 96/14058) disclosed an apparatus (Fig 9/17), an extrusion system for making particles comprising extruder drive motor, controls cooling and temperature controls, feed hopper, pelletzer, rotating cutter (page 21, lin 29-30; continuing to page 22, lin 1-10).

Oshlack disclosed the method of manufacturing particulates (page 23, lin 10 and page 33, lin 15-28 to page 34, lin 1-5) and forming hard gelatin capsules formulation wherein the temperature employed is 83 degrees (page 23, lin 17, 105 degrees, page 24, lin 21-23); and wherein the extruded filaments or strands are congealed and cut into desired size (page 23, lin 29). Oshlack et al disclosed the use of acrylic polymer, Edudragit (page 24, lin 19-22) or other polymers (page 14, lin 28-30 to page 15, lin 1-5).

Oshlack also disclosed that the extruded multiparticulate system can be in the form of spheroids (page 17, lin 29) and that the extruded multiparticulates can be any geometrical shape within a size range; e.g. beads, microspheres, seeds, pellets (page 18, lin 5-9).

One of ordinary skill would be motivated to prepare particulates of drug (e.g. opioids) using melt extrusion technique as disclosed by Oshlack (WO '745). One of ordinary skill would expect to obtain sustained release opioid formulation that is capable of providing bio-available doses for analgesia in patients (WO '745, page 6 lin 1-5). Therefore, this invention as a whole would have been prima facie obvious to one of ordinary skill at the time the invention was made.

#### **Response to Argument**

Applicant's remarks and arguments have been fully considered but they are not persuasive.

Applicant argues that WO' 058 does not teach spheronization contending that the reference indicates ..”a sustained-release melt extruded multiparticulate formulation which need not be spheronized..”; that WO '058 does not wish to obtain spheroidal particles and that this distinguishes the instant claims from the prior art as the instant claims prefer spheroids.

In response, Oshlack also disclosed that the melt extruded multiparticulate system can be, for example, in the form of granules, spheroids or other pellets depending upon the extruder exit orifice (WO '059, page 17, lin 29)—thus spheroids are contemplated. What applicant considers as a “technically meaningless” statement in the prior art nevertheless is part of the disclosure in the prior art--it may be an important disclosure for one of ordinary skill because as in this case, that statement serves as the basis for making the instant claims obvious as there is a motivation to take advantage of the process to make sustained release formulations that can provide analgesia to patients.

Applicant argues that the instant claims are further distinguished from the prior art, Oshack et al, WO '058 in that there is no disclosure in WO '058 of a particular heating step distinct from the heating in the extruder heating zones where extrusion is carried out as opposed to the instant invention that requires a range of temperature of 20-70 degrees for 30 minutes-150 min.

In response, applicant has not provided any showing of criticality of the temperature and time required to distinguish the instant claims from the prior art. Contrary to applicant's assertions, Oshlack et al, WO '058 disclosed the use of specific temperature (e.g. 83 degree, page 23, lin18; page 27, lin 22), 65 degrees (page 44, lin 1) and 30-200 degrees (page 47, lin 9). The statement in the prior art—“heating said blend to a temperature sufficient to soften the mixture

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sufficiently to extrude the same (page 54, lin 18-20) is evidence that substances of different melting points can be used in the manufacture as also pointed out in the reference (page 47, lin 9).

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

The following prior art is regarded as pertinent to the instant claims and are made part of the record but not currently relied upon for the rejection: Oshlack et al (US 5, 958, 452); teaches extruder heated to requisite temperature to melt the blend in formation of sustained release composition (abstract, col 3, lin 40-50, col 27, lin 40-55 and col 28, lin 35-45). The reference is not relied upon because it is the same as the 'WO '058.


### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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